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Docket No.: 27795-00032USPX
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Axel L. Bernhard et al.

Application No.: 10/734925 Confirmation No.: 2233

Filed: December 12, 2003 Art Unit: 2816

For: ELECTRO STIMULATION TREATMENT APPARATUS AND METHOD Examiner: Not Yet Assigned

CLAIM FOR PRIORITY AND SUBMISSION OF DOCUMENTS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicant previously claimed priority under 35 U.S.C. 119 based on the following prior foreign application filed in the following foreign country on the date indicated:

Country	Application No.	Date
Australia	2002953278	December 12, 2002

In support of this claim, a certified copy of the said original foreign application is filed herewith.

Dated: May 27, 2004

Respectfully submitted,

By Stanley R Moore
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Patent Office
Canberra

I, JULIE BILLINGSLEY, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2002953278 for a patent by SKOP AUSTRALIA PTY LTD as filed on 12 December 2002.

WITNESS my hand this
Twelfth day of December 2003

J. Billingsley

JULIE BILLINGSLEY
TEAM LEADER EXAMINATION
SUPPORT AND SALES

AUSTRALIA

Patents Act 1990

PROVISIONAL SPECIFICATION

Invention Title: **ELECTRO STIMULATION TREATMENT APPARATUS AND METHOD**

The invention is described in the following statement:

ELECTRO STIMULATION TREATMENT APPARATUS AND METHOD

FIELD OF THE INVENTION

The invention relates generally to a method and apparatus for electro stimulation treatment of the body, cells or tissues cultures wherein electrical power is applied to a plurality of probes that are in electrical connection with the subject of the treatment. The invention is particularly suited to the treatment of relatively large areas of the body with electrical currents for cosmetic and/or medical purposes that currently require a relatively high level of manual intervention and operation by a skilled operator.

BACKGROUND OF THE INVENTION

Electro stimulation apparatus that provides micro current treatments gained popularity in the mid 1980's. The advent of electro stimulation treatment apparatus provided medical and cosmetic benefits although they required a relatively high level of intervention by operators providing long periods of "hands on" treatments. Similarly, clients/patients were required to spend relatively lengthy periods of time at clinics in order to receive treatments.

Since the advent of electro stimulation treatment apparatus, it has been generally recognised that there is a need to reduce the requirement for manual operation of the apparatus by a skilled operator. Apart from the requirement to locate sufficiently skilled operators, clinics have recognised that the labour cost of operators represents a significant component of the cost of delivery of these types of treatments. Further, over time, it has been noticed that clients are becoming less willing to spend the time required to attend clinics to receive treatments.

In addition to the problems identified above, there is a further problem in ensuring the efficacy of any treatment provided to a patient.

According to current treatment regimes, the efficacy of any treatment is highly dependent upon the skill and experience of an operator. Treatments are presently applied by placement of probes on the surface of the skin of a patient and whilst signals are applied to the probes they are moved across the surface of the skin. Even with a highly skilled and experienced operator, it is currently impossible to ensure that an area being treated is uniformly exposed to electro stimulation.

Non-uniform exposure of an area requiring treatment will usually result in reduced efficacy of the treatment. In these instances, a patient may require more treatments than necessary to achieve the result they require and hence will necessarily be required to devote more time to receiving treatments than would otherwise be required.

Accordingly, there is a need for an electro stimulation treatment apparatus that reduces the requirement for manual operation by a skilled operator. Further, there is a need for such an apparatus that can provide a greater level of confidence that uniform treatment, or at least prescribed treatment, has been applied for any particular treatment session.

In the past, attempts have been made to provide a treatment apparatus that generates electrical signals and distributes those electrical signals to multiple probes or pads that are in contact with the skin tissue of a patient. Generally, multiple "active" pads are provided that are electrically connected to a power supply and another set of multiple pads are also supplied that provide a return path for electrical current flow. Placement of "active" pads and "return" pads spaced apart on the body or limb of a patient then allows the application of electrical signals to the active pads to cause the flow of electrical current through the area of the body or limb residing between the active and return pads.

Whilst this approach provides for a greater area to be treated, the same electrical signal is applied to all of the active pads at the same time. As a result, there is no assurance with respect to uniformity of application of the electrical currents to the area being treated as certain regions within that area may present a lower impedance path to the flow of electrical current and hence cause a concentration of the treatment through that region to the exclusion or limitation of other regions within the area being treated.

Other attempts to overcome the problems of non-uniform treatment have included systems having numerous power supplies that are connected to sub sets of pads such that placement of a set of active pads on the skin tissue of a patient comprises pads that are connected to different power supplies. Switching the individual power supplies on and off intermittently thus enables some control of the application of the electro stimulation treatment to the area being treated. However, these systems are intended to be used for the application of electro

stimulation to disparate parts of the body, such as the legs and arms, so that these separate areas can be treated simultaneously. If all of the pads are located in a single area then substantial interference is caused between the power supplies.

Accordingly, it is an object of the present invention to provide an apparatus and method for the application of electro stimulation treatments to a treatment subject that provides greater uniformity of treatment as compared with prior art systems. It is a further object of the present invention to provide improved uniformity of treatment as compared with prior art systems whilst retaining either a single power supply or a limited number of power supplies in the treatment apparatus thus maintaining the cost of such an apparatus to a minimum.

Any discussion of documents, devices, acts or knowledge in this specification is included to explain the context of the invention. It should not be taken as an admission that any of the material formed part of the prior art base or the common general knowledge in the relevant art on or before the date of filing of this application.

SUMMARY OF THE INVENTION

In one aspect, the present invention provides an electro stimulation system including:

an electrical power supply;

a switching device;

a switching control device connected to the switching device; and

connection probes;

wherein the electrical power supply is connected to the input of the switching device which, under the control of the switching control device, directs electrical power to one or more outputs of the switching device that are connected to connection probes placed in electrical connection with the subject of the treatment.

Preferably, the electrical power supply is connected to a current control circuit such that electrical current supplied to the subject of the treatment is regulated or controlled. Further, the switching device may be a multiplexing device which is the preferred form of the switching device which is connected to a multiplexing control device.

Preferably, connecting probes that provide an electrical current return path to the apparatus are also in electrical connection with the subject of the treatment. In the instance of using an apparatus according to a preferred embodiment for electro stimulation of skin tissue, "active" connecting probes and "return" connecting probes are connected to the skin tissue of the patient such that the supply of electrical signals to the skin of the patient through the multiplexing device causes electrical current to flow between the active probe and one or more "return" probes.

In an embodiment, the arrangement of "active" probes and "return" probes primarily determines the path of electrical current flow through an area to be treated. In a particularly preferred embodiment of the apparatus, the determination of the probes as either "active" or "return" type probes is determined by the multiplexing control device. In this embodiment, each probe is connected to the output of a first multiplexing device and the input of a second multiplexing device. The first multiplexing device connects one or more probes to the output of the current control circuitry whilst the second multiplexing device connects one or more probes to an electrical current return path. Of course, in use, a probe should only be either an active or return type probe at any one time. Any particular probe may be switched many times between the two types during a treatment but any individual probe should not be selected as an active probe (ie connected to the output of the current control circuitry through the first multiplexer) at the same time that it is selected as a return probe (ie connected to the return path through the second multiplexer).

The connection arrangement of probes and the ability to control the type of the probe at any particular time during a treatment enables the provision of complex electrical current distributions amongst a set of probes connected to an area for treatment.

In another aspect, the present invention provides a method of providing electro stimulation treatment to a patient including the steps of:

(a) attaching a plurality of electro stimulation probes in electrical connection with a treatment subject;

(b) selecting one or more of the probes for connection to an electrical power supply thereby causing said one or more probes to become active probes;

(c) selecting one or more of the probes for connection to an electrical current return path thereby causing said one or more probes to become return probes;

(d) connecting said one or more active probes to the electrical power supply and said one or more return probes to the electrical current return path thus causing an electrical current to flow between said active and return probes; and

(e) altering the selection of active and return probes; and

(f) repeating steps (d) and (e) until completion of the treatment.

Preferably, the selection of active and return probes is varied throughout a treatment and in one preferred embodiment, only a single probe is active at any one time whilst all other probes are selected as return probes.

During a treatment a probe should only be either an active probe or a return probe. However, for calibration of the apparatus, a probe may be selected as an active probe and a return probe simultaneously.

For the purposes of this specification, the term probe is intended to include any apparatus capable of providing an electrical connection to the subject of a treatment. For example, the connection could be as a result of direct contact with, or penetration into, the treatment subject or indirect contact by means of an electrolytic solution. Further, the electrical connection could be implemented without any contact such as an inductive connection.

BRIEF DESCRIPTION OF THE DRAWINGS

A preferred embodiment of the invention will now be described which should not be considered as limiting any of the statements in the previous section. The preferred embodiment will be described with reference to the following Figures in which:

Figure 1 is a circuit diagram of two separate power supplies and respective current control circuits for the regulation of current supply to the skin tissue of a patient;

Figure 2 is a circuit diagram of four separate multiplexing devices;

Figure 3 is a circuit diagram of a microprocessor and a digital to analogue converter;

Figure 4 is a circuit diagram of a display that is connected to the microprocessor of Figure 3; and

Figure 5 is a circuit diagram of a convention power supply arrangement for supplying power to the devices in Figures 1 to 4.

DETAILED DESCRIPTION OF THE INVENTION

With reference to Figure 1, two power supplies and respective current control circuitry are detailed. In this scheme the output of a power supply is applied to the tissue, however the opposite polarity signal is not derived from the ground or PCB voltage reference signal directly. Instead the current path flows from the positive connection at the power supply through the skin tissue and returns through a controlling transistor, through a sensing resistor to ground. At the junction of the sensing resistor and the transistor emitter is a small voltage that is directly proportional to the current flow through the skin tissue. This voltage is applied to the non-inverting input of an operational amplifier, whose other input is a voltage representing the desired actual current flow. The output of the amplifier controls the voltage at the base of the transistor which directly regulates the current automatically. This circuit is a current regulator.

This scheme leads to superior signal control, and thus more efficient treatment, and also greatly enhances the ability to effectively switch signals between multiple sources and destinations. In this scheme, high absolute voltages are maintained on the tissue, which promote improved current flow.

In this configuration it is possible to have a multiplicity of current regulator (CR) circuits operating upon a single power supply. For a single CR there is only one possible current path, from the power supply electrode (PSE) to the CR electrode (CRE), this current will be that set by the voltage on the amplifier inverting input. This voltage is called the Waveform Control Voltage (WCV). If, however there are many CRs each with a CRE, there will be current flow between the PSE and each CRE that is precisely set by the WCV for each CR.

This is one embodiment that represents a simple solution to improving signal distribution (ie a single power supply unit with many current regulator circuits). The WCV allows complex current waveforms to be generated in the skin tissue. By varying the WCV signal in a specified and preferred pattern, the current between a CRE and a PSE will match this waveform.

The opposite scenario of a single current regulator and many power supply units is also explored. In this scenario the WCV sets the total current flow for the system. Since electrical current will flow through the path of least resistance, it is difficult to predict the actual signal coverage. This is one embodiment although not a preferred embodiment of the invention.

To advance this to the next logical phase it may be seen that if the location of PSE were fixed, the overall signal coverage would comprise a series of lines between the number of CREs used. Although this improves upon existing techniques, it does not provide a significant improvement to the uniformity of signal coverage. It can be observed that if the circuit were able to change the position of the PSE automatically, coverage could be improved. In this simple scenario a high voltage multiplexer integrated circuit (HVMUX) can be used.

Inclusion of a multiplexing device that can receive low voltage signals to effect control of the device enables signals from a low voltage control system such as a microprocessor, to control the distribution of high voltage signals. In one preferred embodiment the HVMUX might be of 8:1 configuration. This means that either one of 8 input signals can be selectively switched to one output signal (eg one of eight pads can be selected as a return pad) or that one input signal can be selectively switched to one of 8 output signals (eg any one of eight pads can be selected as an active pad for the supply of an electrical signal to skin tissue).

Of course, there are variations of this arrangement, including 2 x 4:1, 16:1 etc. If an HVMUX were used to switch the power supply signal to one of eight possible PSE pads, then even more uniform signal coverage can be obtained. This configuration represents one of the preferred embodiments for a single power supply. (1PSU, many CR's and many PSE's) The opposite scenario is also possible (many PSU's, 1CR and many CREs) despite not being a preferred embodiment of the invention.

To improve further upon this it can be seen that by applying a single CR and a single PS to one or more HVMUX circuits that a similar effect of greatly improved signal coverage can be obtained. However, in this case there is only one signal path at any time.

Other possible scenarios include:

- Many PSU's each with 1 CR HVMUX allowing switch if just CR, just PS or both;
- 1 PSU, many CRs HVMUX allowing switching of CR, PS or both; or
- Many PSU's each with 1 or Many CR HVMUX allowing all CR, PS or both to be switched.

Any of the preferred embodiments of the invention that has more than a single CR is capable of generating different current waveforms, by applying different WCV signals to them. The effect of this is to generate more complex waveforms in the tissue than the simple waveforms defined by the WCVs.

Further, since the actual voltage of each PSU may be individually set, the differences between PSU voltages create additional complex signals in the tissue.

Each WCV is created wholly independently of the others by a microprocessor circuit (U1, Figure 3). This microprocessor in a preferred embodiment of the invention also controls the user interface to the apparatus.

Waveforms may be generated or selected for generation from a variety of sources. A preferred set of waveforms may be pre-stored in the microprocessor, or a list of waveform attributes may be selected by the user from a menu or similar collection of predefined values. Similarly, the user may be allowed to define the precise waveform characteristics they require, in which case the microprocessor may calculate the relevant parameters of the waveform in real time.

In a preferred embodiment of the invention, a microprocessor controls one or more independent power supplies and an array of multiplexing/switching chips. The power supply provides an electrical signal and ground. The switching chip is capable of switching a signal or the ground to 1 of 8 pins of the multiplexing device. Thus, in the preferred embodiment, one multiplexing device was used for the switching of the signal and another multiplexing device was used for the switching of the ground to 5 (or more) pins.

Either the signal or the ground can be switched to one of the 8 pins first, then the other may be switched to any of the remaining 7 pins. Thus placing 5 (or more) pads around the area to be treated, a sophisticated switching pattern may be established to stimulate any tissue within the area effectively by activating up

to 20 path for 5 pads (5x 4 possibilities), 30 paths for 6 pads (6x5 possibilities), 42 paths for 7 pads (7x6 possibilities) or 56 paths for 8 pads (8x7 possibilities).

Further 2, 3, 4 or more independent power supplies can be switched via 2 multiplexing devices and stimulate more areas or create more intricate and sophisticated stimulation patterns.

Providing a current controlled signal to one pin of the first multiplexing device (U4 Figure 2) and a return path to one pin of the second multiplexing device (U5 Figure 2) allows the combination of two padded areas into one and an even more sophisticated stimulation pattern. Similarly more power supplies may be switched similarly allowing a much larger number of current paths.

CONCLUSION

The present invention embodies many advantages including a significant reduction with respect to the skill level of an operator providing electro stimulation treatments. The improved apparatus and method of the present invention enable the establishment of complex current paths through an area under treatment without any skill or knowledge of these types of treatments. Accordingly, application of this type of treatment with an apparatus of the present invention ensures that an area under treatment receives a significantly more uniform treatment as compared with prior systems that rely primarily upon the skill of an operator.

With an improved electro stimulation system according to the present invention, it is possible for non skilled users, such as the patients themselves, to administer treatments. In this respect, a relatively simple set of instructions may be provided guiding the patient with regard to the placement of pads on the skin tissue and the selection of an appropriate treatment program. A significant advantage in this respect is that patients are no longer required to attend a clinic in order to receive treatments and may apply their own treatment in the comfort of their home.

The improvements provided by an apparatus according to the present invention are achieved without significantly increasing the number of power supplies contained within the apparatus. As such, an electro stimulation system according to the present invention may be manufactured within an acceptable

cost such that the device is considered affordable for purchase and home use by consumers.

An improved apparatus and method according to the present invention further enhances medical aspects of this type of treatment including the healing of wounds, decubitus, fractures etc by activating circulation and the tissue activity. It is also possible that an apparatus and method according to the present invention may be used to assist the process of generating or growing tissue and/or cells for skin grafts. This aspect is particularly beneficial in relation to the treatment of burn victims or any other patient suffering the effect of the removal of skin tissue.

DATED this 12th day of December 2002

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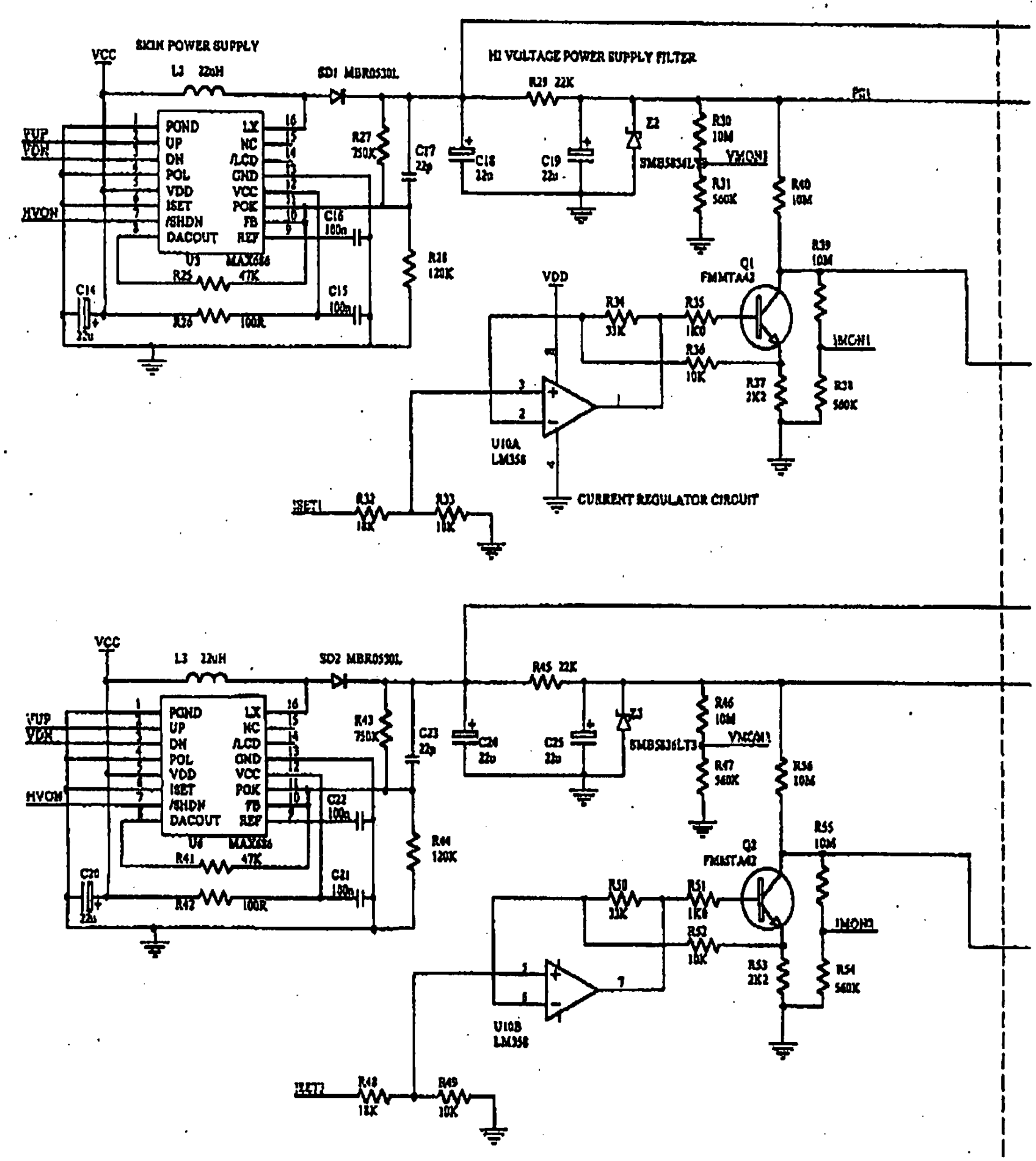
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UP
DN
POL
VDD
ISET
/SHDN
DACOUT
LX
NC
/LCD
GND
VCC
POK
FB
REF
U5 MAX686
U6 MAX686
VUP
VDN
HVON
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R35 1K0
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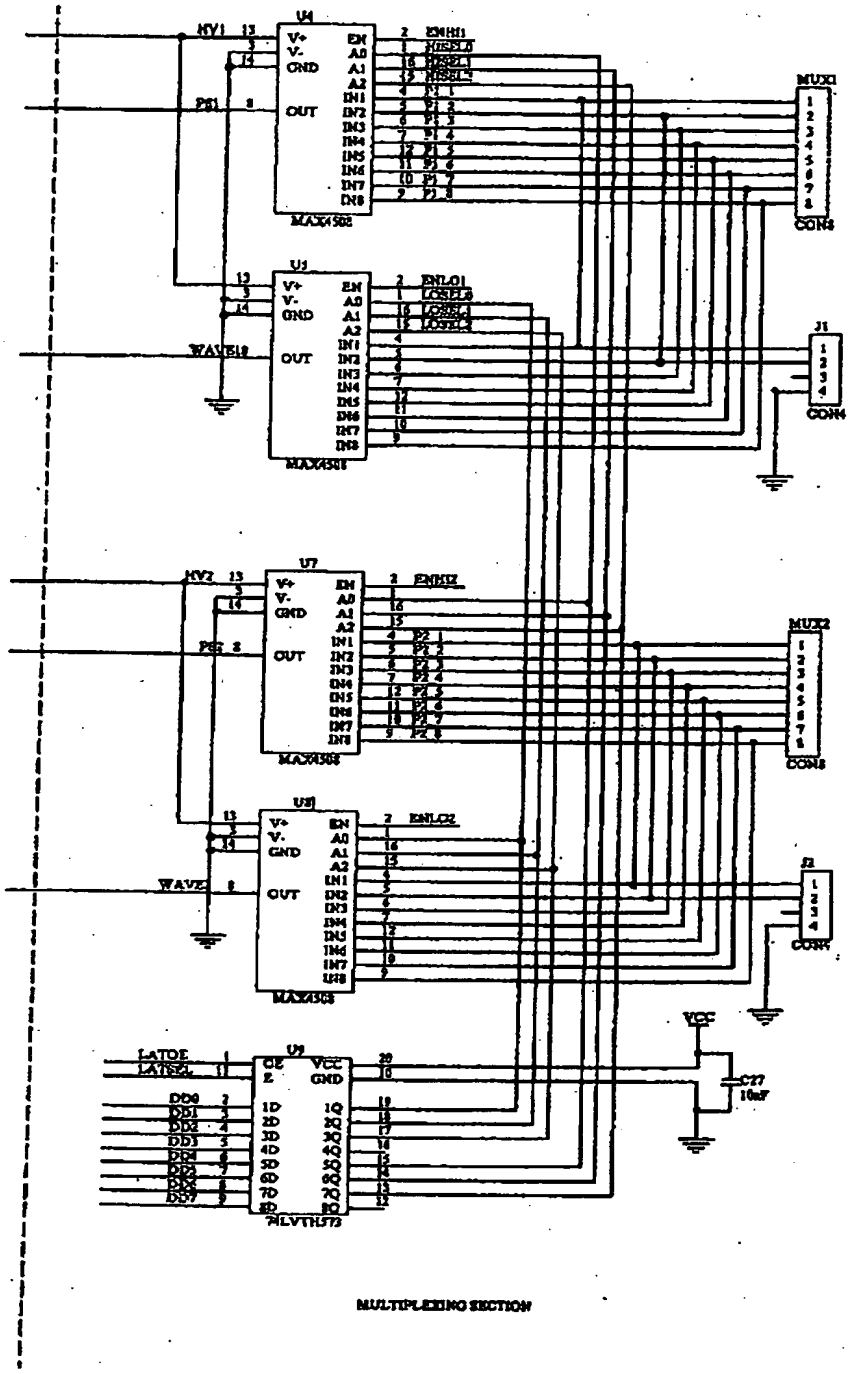
IMON1
IMON2
VMON1
VMON2

Figure 1



MULTIPLEXING SECTION

Figure 2

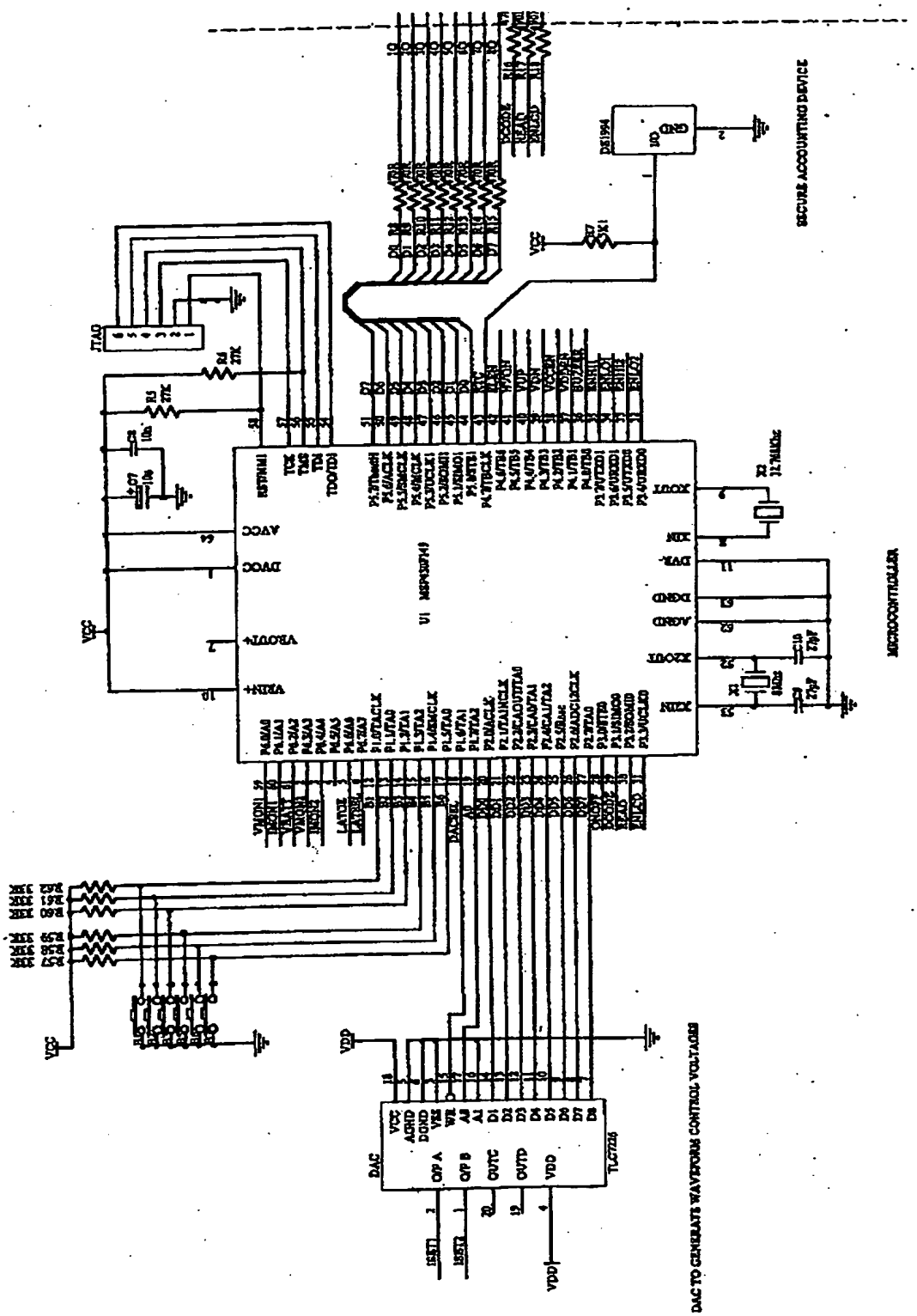


Figure 3

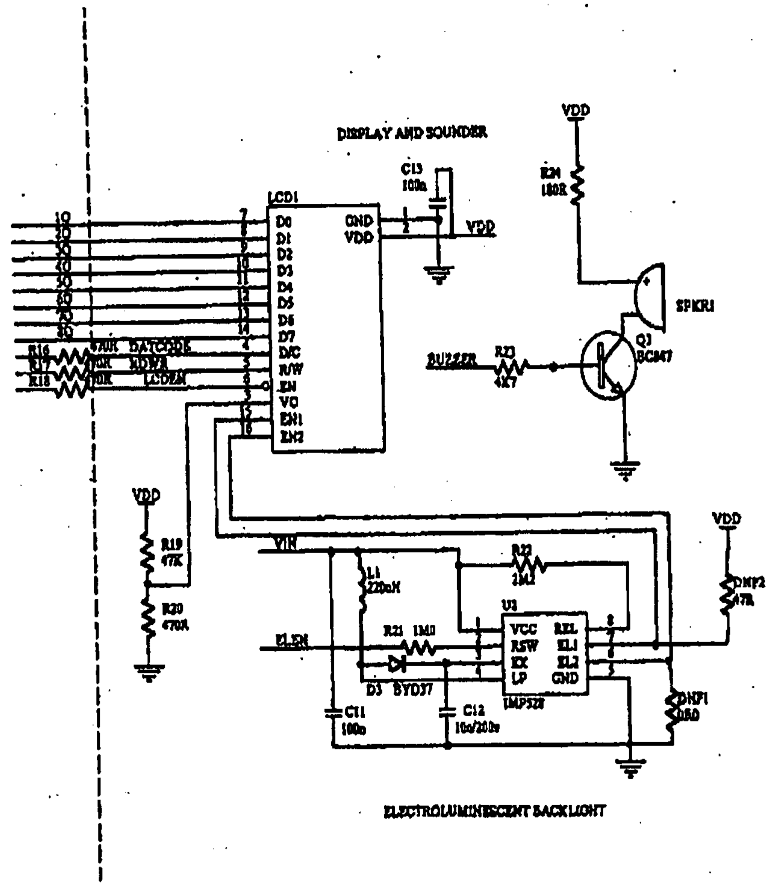


Figure 4

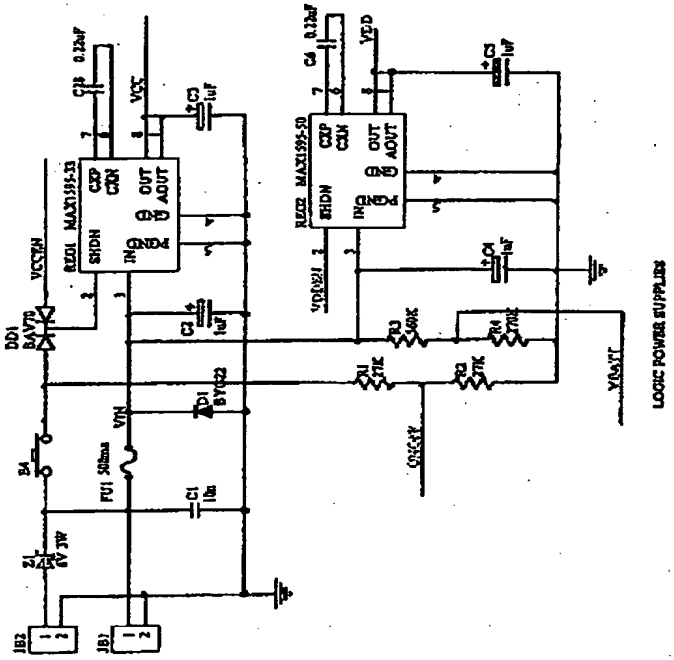


Figure 5